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Attorney Docket No. 23135-510CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Masternak *et al.*

SERIAL NUMBER: 09/840,243

EXAMINER: A. Decloux, Ph.D.

FILING DATE: April 24, 2001

ART UNIT: 1644

FOR: TRANSCRIPTION FACTOR OF MHC CLASS II GENES, SUBSTANCES CAPABLE OF
INHIBITING THIS NEW TRANSCRIPTION FACTOR, AND MEDICAL USES OF THESE
SUBSTANCES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Boston, Massachusetts
September 8, 2003

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DECLARATION OF PRIOR INVENTION UNDER 37 C.F.R. §1.131

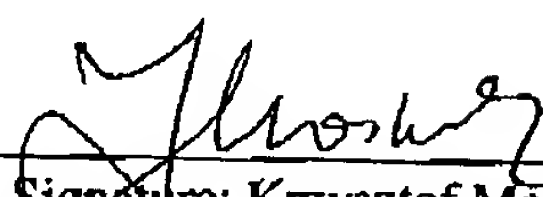
We, Krzysztof Masternak, Walter Reith and Bernard Mach, hereby declare and state as follows:

1. We are aware that in the non-final Office Action dated March 25, 2003, in the above-identified application ("the Application"), the Examiner has rejected claims 1-3, 5-6 and 62-66 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,989,863 ("Tang"). This declaration is being made to establish reduction to practice of the inventions described in the Application under 37 C.F.R. 1.131(c)(1) at a date prior to October 14, 1998, the filing date of Tang.
2. We, Krzysztof Masternak, Walter Reith and Bernard Mach, invented the inventions described in the Application, and we hereby declare that in Geneva, Switzerland, we reduced to practice the invention described in the pending claims of the instant application before October 14, 1998, the effective filing date of Tang. A copy of the pending claims as amended in Applicants' Response and Amendment filed on August 25, 2003, including rejected claims 1-3, 5-6 and 62-66, is attached hereto as Exhibit 1.
3. Reduction to practice of the invention described and claimed in at least amended claims 1-3 and 62 of the Application, is demonstrated by the documents attached hereto as Exhibits 2-7. Exhibit 2 is a copy of an article, Masternak *et al.*, Nature Genetics 20:273-277 (1998 (a publication from our laboratory) ("Masternak"), which is the scientific publication that

corresponds to the instant patent application (which claims priority to our October 24, 1998 filing in Europe).


4. Masternak (Exhibit 2), which was submitted to *Nature Genetics* on August 21, 1998, accepted on October 5, 1998 and published in November 1998, describes the identification of *RFXANK*, the gene encoding a novel RFX-associated transactivator that is mutated in the majority of MHC Class II deficiency patients in complementation group B. Masternak identified the amino acid sequence of a novel 260 amino acid protein, RFXANK (*See pp. 273-74, Figure 2*). The amino acid sequence disclosed in Masternak corresponds to the amino acid sequence shown in Figure 2 of the Application. Masternak also demonstrated that expression of *RFXANK* restored MHC-II expression in cells from patients from complement group B (*See p. 274, Figure 3*). Accordingly, Masternak demonstrates the reduction to practice of the invention described in at least amended claims 1-3 and 62 of the instant application before October 14, 1998, the effective filing date of Tang.
5. Further, Exhibit 3 confirms that the amino acid and nucleotide sequences for human RFXANK and murine RFXANK shown in Exhibits 4-7 (Exhibit 4 is the Homo Sapiens RFXANK mRNA sequence; Exhibit 5 is the Homo Sapiens RFXANK amino acid sequence; Exhibit 6 is the Mus musculus Rfxank mRNA sequence; and Exhibit 7 is the Mus musculus Rfxank amino acid sequence) were filed with GenBank on September 25, 1998, prior to the October 14, 1998 filing date of Tang. Accordingly, these documents demonstrate the reduction to practice of the invention described in at least amended claims 1-3 and 62 of the instant application before October 14, 1998, the effective filing date of Tang.
6. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Applicant(s): Masternak et al.
Appl'n No. 09/840,243

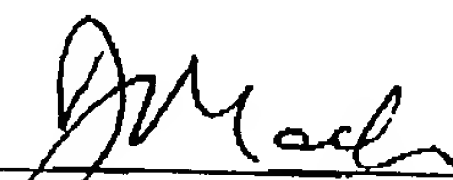

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